EXHIBIT 46

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Memorandum

Date OCT 20 1992

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Cost of Dialysis-Related Drugs (A-01-91-00526)

To William Toby, Jr.
Acting Administrator
Health Care Financing Administration

The attached final management advisory report summarizes the results of our review of the Health Care Financing Administration's (HCFA) proposal to change the methodology for reimbursing separately billable drugs under Medicare's end stage renal disease (ESRD) program. On June 5, 1991, HCFA published a proposal to change the methodology for reimbursing drugs under Medicare's ESRD program to 85 percent of the national average wholesale price (AWP) of the drug as published in the Drug Topics Red Book and similar price listings. At the request of HCFA, we initiated a review to (1) determine the impact of paying dialysis facilities for drugs based on the proposed regulation and (2) obtain the necessary data to include payment for certain high volume separately billable dialysis-related drugs under the prospective composite rate.

Subsequently, HCFA published final regulations (effective January 1, 1992) basing the reimbursement for separately billable drugs on single-source and multiple-source drugs as follows:

> **Single-Source Drugs** - The lower of the estimated acquisition costs (EAC) or the AWP. The EAC is based on surveys of the actual invoice prices paid for the drug.
>
> **Multiple-Source Drugs** - The lower of the EAC or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

The review results indicate that dialysis facilities purchase separately billable drugs significantly below the AWP. Instructing the Medicare fiscal intermediaries (FI) to set the reimbursement limit at the EAC rather than the AWP for selected drugs appears to be a reasonable course of action for HCFA to take in controlling Medicare program expenditures. Some facilities, however, still need to be encouraged to seek the lowest possible price for the purchase of drugs. With regard to the second objective, we were unable to identify any high volume separately billable drug that

was administered enough to include in the composite rate. However, as an alternative, HCFA should consider including the cost of all separately billable drugs into the composite rate to save on administrative costs and reduce payment errors.

We are recommending that HCFA: (1) provide the necessary guidance to the Medicare FIs to ensure a timely implementation of the EAC provision of the new Medicare drug regulations, (2) encourage providers to purchase their drugs from the most economical source, and (3) consider a methodology for folding the costs of all separately billable drugs into the composite rate.

In response to our draft report, HCFA indicated agreement with recommendations one and two and stated that it is in the process of developing a Medicare Carrier Manual instruction to limit drug payment to the lower of the AWP or the EAC.

Regarding the third recommendation, HCFA has deferred comment and requested information on the correlation of drug use patterns at hospital-based facilities. In addition, HCFA has requested the variation in the cost of separately billable drugs to total facility costs among the facilities surveyed. Additional comments addressing this issue follow the RECOMMENDATIONS section of our report.

Please advise us, within 60 days, on actions taken or planned on our recommendations. If you have any questions, please call me or have your staff call George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 966-7104. Copies of this report are being sent to other interested top Departmental officials.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COST OF DIALYSIS-RELATED DRUGS

OCTOBER 1992 A-01-91-00526

DEPARTMENT OF HEALTH & HUMAN SERVICES — Office of Inspector General

Memorandum

Date OCT 20 1992

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Cost of Dialysis-Related Drugs (A-01-91-00526)

To William Toby, Jr.
Acting Administrator
Health Care Financing Administration

This final management advisory report summarizes the results of our review of costs for dialysis-related drugs. On June 5, 1991, the Health Care Financing Administration (HCFA) published a proposal to change the methodology for reimbursing drugs under the Medicare end stage renal disease (ESRD) program to 85 percent of the national average wholesale price (AWP) of the drug as published in the Drug Topics Red Book (Red Book) and similar price listings. At the request of HCFA, we initiated a review to (1) determine the impact of paying dialysis facilities for drugs based on the proposed regulations and (2) obtain the necessary data to include payment for certain high volume separately billable dialysis-related drugs under the prospective composite rate.

On November 25, 1991, HCFA published final regulations (effective January 1, 1992) basing the reimbursement for separately billable drugs on single-source and multiple-source drugs as follows:

Single-Source Drugs - The lower of the estimated acquisition costs (EAC) or the AWP. The EAC is based on surveys of the actual invoice prices paid for the drug.

Multiple-Source Drugs - The lower of the EAC or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

Prior to the new regulations, ESRD facilities were reimbursed at the lower of the facility's customary charge, the facility's actual charge, or the AWP.

Our review of 30 randomly selected dialysis facilities disclosed that most of the separately billable drugs administered during May 1991 were purchased at prices below the AWP. The median cost for two of the more frequently administered brand name drugs ranged from 15 percent to 20 percent less than AWP. Instructing the Medicare fiscal intermediaries (FI) to set the reimbursement limit at the EAC rather than the AWP for selected drugs appears to be a reasonable approach to controlling Medicare program expenditures.

Based on our analysis, the majority of facilities included in our review will recover their costs under the EAC provision. Our review also showed that the acquisition cost (invoice price) for drugs did vary by facility and, as such, drug costs for some facilities under the new regulations could be higher than the EAC. However, reimbursement under the Medicare program is based on the premise that the provider of services will not pay more than the going price and will seek to economize by minimizing its costs. Accordingly, facilities with costs that are above the EAC must be encouraged to become more prudent buyers of drugs and seek the lowest possible price.

We are also concerned about the implementation of the EAC provisions by the FIs. A review conducted by the Office of Inspector General (OIG) of separately billable drugs (CIN: A-01-90-00502) disclosed a material weakness in the system of internal controls at the FIs for the payment of separately billable drugs that resulted in over $15 million in program overpayments. Accordingly, controls are needed to ensure that these same weaknesses do not occur when the FIs implement the new EAC provisions.

In regards to the second review objective, we identified as many as 35 separately billable drugs that were administered to ESRD patients during the month of May 1991 at a random sample of 30 facilities. However, we only found three drugs (Calcijex, Imferon, and Vancocin/Vancomycin) that were administered by more than 50 percent of the sampled facilities. Even for those three drugs, the utilization varied significantly from one facility to another during the month of May 1991. It was evident from our analysis and discussions with ESRD facility administrators that the drug treatment patterns were not consistent among ESRD patients and that the types of separately billable drugs administered to patients change as new drugs become available. Consequently, facilities do not consistently administer the same type of drugs to its patients. Therefore, we were not able to develop an equitable method for modifying the composite rate for any one particular separately billable drug.

As an alternative, HCFA could consider a methodology for folding the costs of all separately billable drugs into the composite rate since these drug costs only represent 3.2 percent of total facility costs. If this method is adopted, HCFA should

utilize the most recent audited facility cost data. Having a comprehensive rate which includes all the costs relating to a dialysis treatment would save administrative costs and reduce the payment errors that have occurred in processing claims for separately billable drugs at the FIs.

We are recommending that HCFA: (1) provide the necessary guidance to the FIs to ensure a timely implementation of the EAC provision of the new Medicare drug regulations, (2) encourage providers to purchase drugs from the most economical source, and (3) consider a methodology for folding the costs of all separately billable drugs into the composite rate.

In response to our draft report, HCFA indicated agreement with recommendations one and two and stated that it is in the process of developing a Medicare Carrier Manual instruction to limit drug payment to the lower of the AWP or the EAC.

Regarding the third recommendation, HCFA has deferred comment and requested information on the correlation of drug use patterns at hospital-based and free-standing facilities. In addition, HCFA has requested the variation in the cost of separately billable drugs to the total facility costs among the facilities surveyed. Additional comments addressing this issue follow the RECOMMENDATIONS section of this report.

BACKGROUND

Health Insurance for the Aged and Disabled (Medicare), title XVIII of the Social Security Act, as amended, is a broad program of health insurance that is administered by HCFA. Medicare includes coverage for eligible persons suffering kidney (renal) failure under its ESRD program. The HCFA utilizes a prospective method of payment for dialysis services. Under this system, HCFA establishes a composite rate, per treatment, to reimburse independent renal dialysis facilities and hospital-based facilities. The Medicare program pays 80 percent of the composite rate, and payment of the remaining 20 percent (coinsurance) is the responsibility of the ESRD beneficiary. The composite rate is a comprehensive payment for all services related to dialysis treatment except for physicians' patient care services, blood, and certain drug and laboratory services that are separately billable.

Reimbursement to independent dialysis facilities for separately billable services is based on prescribed limits set forth in 42 CFR parts 405 and 415. Effective January 1, 1992, reimbursement for single-source separately billable drugs is based on the lower of the EAC or the national AWP of the drug. For multiple-source drugs, payment is based on the lower of the EAC or the median price for all sources of the

generic form of the drug. The EAC is determined based on surveys of the actual invoice price paid for the drug. In calculating the EAC of the drug, the carrier may consider factors such as inventory, waste, and spoilage. In addition to the payment for the drug, a payment is made for the cost of the supplies used to administer the drug (e.g., syringe). However, no separate payment is to be made for the staff time used to administer drugs. These services are reimbursed through the ESRD composite rate.

Based on 1990 cost report information submitted by 23 of the 30 sampled facilities, we determined that separately billable drug costs accounted for 3.2 percent of the total facility costs. For the remaining seven facilities, we were unable to determine their separately billable drug costs.

Hospital-based dialysis facilities are reimbursed for separately billable services through the hospital cost report settlement process. Medicare FIs are responsible for processing claims for separately billable drug and blood services submitted by dialysis facilities.

METHODOLOGY

On June 5, 1991, HCFA published a proposal to change the methodology for reimbursing drugs under the Medicare ESRD program to 85 percent of the national AWP of the drug as published in the Red Book and similar price listings. At the request of HCFA, we initiated a review to (1) determine the impact of paying dialysis facilities for drugs based on the proposed regulations and (2) obtain the necessary data to include payment for certain high volume separately billable dialysis-related drugs under the prospective composite rate.

On November 25, 1991, HCFA published final regulations (effective January 1, 1992) basing the reimbursement for separately billable drugs on single-source and multiple-source drugs as follows:

> **Single-Source Drugs** - The lower of the EAC or the AWP. The EAC is based on surveys of the actual invoice prices paid for the drug.
>
> **Multiple-Source Drugs** - The lower of the EAC or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

To accomplish our objectives, we randomly selected 30 independent dialysis facilities using a stratified sampling plan that included 10 small, 10 medium, and 10 large facilities (*see Appendix I*). We judgmentally selected the month of May 1991, as the time frame for our analysis. Nothing came to our attention that would indicate that the treatment pattern of the patient population differed from month to month.

For each facility, we determined which separately billable drugs were administered, how often the drug was given, and the invoice price of the drugs paid during May 1991. Frequently administered drugs identified were evaluated individually for each facility to determine if the facility would recover its cost under the revised system of reimbursement.

Information regarding separately billable drugs and the frequency of administration was obtained from medical records, billing records, computer extracts of the medical records, and discussions with ESRD facility administrators and nurses. We conducted on-site reviews at 21 of the sampled facilities. For the remaining nine facilities, we sent out a facility questionnaire to obtain the requested information.

Hospital-based dialysis facilities were not included in the review because they are reimbursed through the hospital cost report settlement process as previously noted. Our review also did not address the issue of inventory cost, waste, or spoilage because of the lack of criteria available to quantify such costs.

We also obtained cost and dosage information regarding the drug Epogen which is billed outside the composite rate at a reimbursement rate of $11.00 per 1,000 units administered. The results of this analysis were not included in this review but will be addressed in a separate report.

Our review was conducted from July 1991 to December 1991 at selected dialysis facilities, the HCFA central office in Baltimore, Maryland and the Boston regional office of the OIG. On April 30, 1992 we provided HCFA with a copy of our draft report. The HCFA's written comments are appended to this report (see *Appendix IV*) and are summarized starting on page 9.

RESULTS OF REVIEW

Impact of the EAC Provisions on Separately Billable Drugs

Almost all of the separately billable drugs were purchased from drug wholesalers. Our analysis of drug invoice prices indicated that 28 of the 30 sampled facilities purchased separately billable drugs at prices less than the AWP. The median cost for two of the more frequently administered brand name drugs ranged from 15 percent to 20 percent less than the AWP. We did identify a few instances where facilities, on occasion, purchased drugs from the local pharmacy at higher prices. For instance, one facility purchased 1 gram of Vancomycin at $41.18, which was $10.04 higher than the AWP of $31.14. Our review also showed that the acquisition cost (invoice price) for drugs did vary by facility. However, as shown in Appendix II, the lowest price was not always associated with the larger facilities. The two lowest prices for Calcijex ($6.19 and $5.90) were obtained by a small and medium sized facility.

Under the new drug regulations, separately billable drugs will be reimbursed based on the lower of EAC or AWP. The EAC is determined based on surveys of the actual invoice prices paid for the drug by facilities. To comply with the new regulations, we developed an EAC for the more frequently administered separately billable drugs using the median invoice price obtained from the 30 dialysis facilities. The following chart illustrates the impact of the new regulations on the reimbursement rate to the sampled facilities:

Drugs/Dosage	EAC	AWP	Payment Difference	Number of Facilities At or Below EAC[1]	Number of Facilities Above EAC
Calcijex 1 MCGM	$ 7.34	$ 9.18	$ 1.84	19	7
Imferon 2 ML	$10.19	$11.99	$ 1.80	9	9
Vancocin/ Vancomycin 500 ML[2]	$ 5.00	$19.17	$14.17	12	9

NOTES

1 *Not all facilities administered or purchased the drug in the same dosage. To ensure adequate comparison, we limited our analysis to only 1 month, May 1991, and the same dosage.*

2 *This drug is a multiple-source drug. We used the median AWP for the generic drug.*

As shown above, Medicare program expenditures for separately billable drugs should be reduced if the EAC is properly implemented.

Even though the reimbursement rate will be reduced, our analysis disclosed that the majority of facilities included in our review will recover its costs under the EAC provision. On the other hand, the new regulations would adversely affect some facilities whose costs were above the EAC. However, the implementation of the EAC should encourage those providers to follow the prudent buyer concept in order to obtain lower prices. In any event, the EAC provision should not significantly affect

the financial status of individual facilities because separately billable drug costs account for only 3.2 percent of the total facility costs.[1]

Prior to the new drug regulations, Medicare FIs were required to reimburse independent dialysis facilities the lower of the facility's customary charge, the facility's actual charge, or the AWP. An OIG review (CIN: A-01-90-00502) identified a material weakness in the system of internal controls that resulted in significant overpayments ($15 million) made by FIs for separately billable drugs. Accordingly, we are concerned that controls are established to ensure that the EAC is properly implemented by the FIs to prevent overpayments from occurring.

Frequency of Use of Separately Billable Drugs

The HCFA requested that we obtain frequency of use data on separately billable drugs to assist in identifying high volume drugs for inclusion in the composite rate. At the time of our review, HCFA had not yet implemented a uniform coding system to identify separately billable drugs as recommended in our nationwide review (CIN: A-01-90-00502), issued July 29, 1991. Accordingly, we used patient medical and billing records to accumulate the data. Most of the facilities reviewed used 10 or less separately billable drugs during the month of May 1991. A few facilities used more, but the frequency of use of most drugs was very limited. Appendix III contains the names of 35 separately billable drugs used by at least 1 facility.

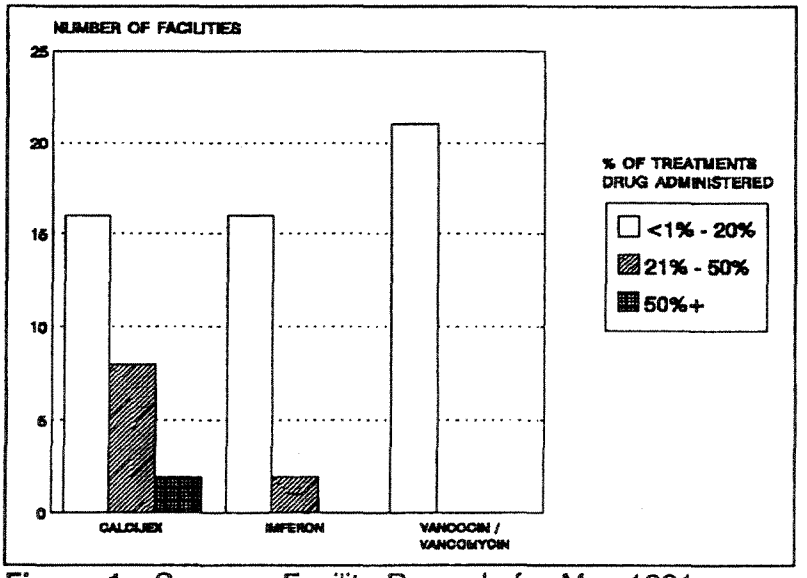

Figure 1 - Source: Facility Records for May 1991

We identified three separately billable drugs that were used by more than half of the facilities. Calcijex is used to combat bone disease in renal patients. Imferon is an iron supplement. Vancocin/Vancomycin is an antibiotic. Calcijex was used at 26 facilities,

[1] Based on 1990 cost report information submitted by 23 of the 30 sampled facilities. For the remaining seven facilities, we were unable to determine their separately billable drug costs.

Vancocin/Vancomycin at 21, and Imferon at 18. However, as Figure 1 indicates, usage patterns vary greatly among facilities. For instance, our analysis of drug usage patterns in May 1991 showed that Calcijex ranged from a low of less than 1 percent of treatments to a high of 60 percent. Imferon usage, as a percent of treatments, ranged from less than 1 percent to 32 percent and Vancocin/Vancomycin from less than 1 percent to 15 percent.

In addition, our analysis and discussion with ESRD facility administrators indicated that the type of separately billable drugs administered changes as new drugs become available. The introduction of Epogen, a red blood cell producing drug, has caused a marked decrease in the use of steroid-type drugs such as Deca-Durabolin and Nandrolone Decanoate used to increase red blood cell production in dialysis patients. Conversely, the widespread use of Epogen, which requires a sufficient level of iron stores, has increased the use of Imferon which builds up the patient's iron level. Imferon was used by 18 facilities and would have been used by more and at higher frequencies except that it is not widely available.

Considering the differences in utilization and the introduction of new types of drugs, we were not able to develop an equitable method for modifying the composite rate for any one particular type of separately billable drug. Moreover, developing a reasonable payment amount to be added to the composite rate, that would be fair to all facilities, would be a difficult task in light of all the variables previously identified. As an alternative, HCFA should consider a methodology for folding the costs of all separately billable drugs into the composite rate since these drug costs only represent 3.2 percent of total facility costs. In doing so, HCFA should utilize the most recent audited facility cost data. Having a comprehensive rate, which includes all the costs relating to a dialysis treatment, would also save administrative costs and reduce the payment errors that have occurred in processing claims for separately billable drugs at the FIs.

RECOMMENDATIONS

We are recommending that HCFA: (1) provide the necessary guidance to the FIs to ensure a timely implementation of the EAC provisions of the new Medicare drug regulations, (2) encourage providers to purchase drugs from the most economical source as required by the prudent buyer concept, and (3) consider a methodology for folding the costs of all separately billable drugs into the composite rate.

HCFA Comments

The HCFA, in its response, indicated agreement with recommendations one and two and stated that:

- it is in the process of developing a Medicare Carrier Manual instruction to limit drug payment to the lower of the AWP or the EAC;
- apart from implementing the new payment methodology, no additional action is needed on the part of HCFA.

Regarding recommendation three, HCFA has deferred comment and requested the following information on folding the costs of all separately billable drugs into the composite rate:

- the correlation between hospital-based and free-standing facilities with regard to the use of drugs;
- the variation among the facilities surveyed of the cost of separately billable drugs to the total facility costs.

OIG Response

Regarding hospital-based facilities, we were unable to determine similar cost data because the hospital cost report does not isolate separately billable drug costs. Nevertheless, if HCFA believes that the concept of including all drugs in the composite rate is a worthwhile objective, hospitals should be required to provide the necessary data to use as a basis for revising the composite rate.

For the 23 facilities reporting separately billable drug costs, the percent of those costs to total facility costs ranged from .0007 percent to 10.36 percent. This information was obtained from the 1990 cost reports filed with the FIs. As previously noted, for the remaining seven facilities, we were unable to determine their separately billable drug costs.

APPENDICES

APPENDIX I

INDEPENDENT DIALYSIS FACILITIES SELECTED FOR REVIEW

SMALL

	Name of Facility	City	State
1	Bakersfield Dialysis Center	Bakersfield	CA
2	BMA of Burlington	Burlington	NC
3	BMA of Guayama	Guayama	PR
4	Community Dialysis - Columbia	Columbia	SC
5	Community Dialysis Service - Winter Haven	Winter Haven	FL
6	Dialysis Center of Shreveport	Shreveport	LA
7	Dickson Dialysis Clinic Inc	Dickson	TN
8	Indian River Artificial Kidney Center	Stuart	FL
9	Kansas Nephrology Associates	Hays	KS
10	South Eastern Dialysis Center	Whiteville	NC

MEDIUM

	Name of Facility	City	State
11	Artifical Kidney Center of Suffolk	Suffolk	VA
12	BMA-Dekalb Gwinnett (BioMedical Assoc.)	Decatur	GA
13	BMA of N Philadelphia	Philadephia	PA
14	Carolina Clinic Kidney Center (REN Wilson)	Wilson	NC
15	Dialysis Center - Denver	Denver	CO
16	Inglewood Dialysis Services, Inc	Inglewood	CA
17	Melbourne Kidney Center	Melbourne	FL
18	Opelika Nephrology Referral Center Inc	Opelika	AL
19	San Diego Dialysis Center	San Diego	CA
20	S. Florida Artificial Kidney Center Inc	Miami	FL

LARGE

	Name of Facility	City	State
21	BMA of Springfield	Springfield	MA
22	BMA of Detroit	Detroit	MI
23	Central Florida Kidney Center	Orlando	FL
24	Dallas Kidney Disease Center	Dallas	TX
25	Greenfield Health Systems Corp	Dearborn	MI
26	Mervin W. Perdue Kidney Center	Alexandria	LA
27	Nephro Care Inc	Brooklyn	NY
28	Northern Louisiana Dialysis Center	Monroe	LA
29	Oak Park Community Dialysis Center	Oak Park	IL
30	University of Louisville Kidney Program	Louisville	KY

APPENDIX II

INVOICE PRICE FOR SELECTED DRUGS AT THE DIALYSIS FACILITIES REVIEWED

SEPARATELY BILLABLE DRUG	FACILITY SIZE	PER UNIT COST										NUMBER OF FACILITIES USING DRUG	EAC	AWP
CALCIJEX 1MCGM/ML (S)	SMALL	$7.93	7.52	7.34	7.34	7.34	7.19	7.19	6.19	-	-	8		
	MEDIUM	$7.52	7.34	7.34	7.19	7.19	7.19	7.16	7.02	5.90	-	9		
	LARGE	$7.93	7.71	7.52	7.45	7.34	7.34	7.34	7.27	7.19	-	9		
												26	$ 7.34	$ 9.18
IMFERON 2ML (S)	SMALL	$11.99	11.99	11.40	10.80	9.70	9.45	-	-	-	-	6		
	MEDIUM	$12.98	11.40	10.39	9.99	9.91	8.88	8.11	-	-	-	7		
	LARGE	$12.86	10.80	9.03	8.88	7.51	-	-	-	-	-	5		
												18	$10.19	$11.99
VANCOMYCIN VANCOCIN 500MG (M)	SMALL	$8.33	7.80	4.79	4.59	4.59	3.45	-	-	-	-	6		
	MEDIUM	$12.50	7.80	7.55	5.00	5.00	4.79	4.79	4.75	-	-	8		
	LARGE	$26.61	8.67	7.80	6.82	5.00	4.44	3.89	-	-	-	7		
												21	$ 5.00	$19.17

Notes:
S = Single source drug
M = Multiple source drug
- = Facility did not purchase this drug during sample month.
EAC = Estimated Aquisition Cost was calculated using the median invoice price.
AWP = Average Wholesale Price is the median Red Book price for the generic form of the drug.

APPENDIX III

LIST OF SEPARATELY BILLABLE DRUGS

Albumin
Ancef
Benadryl (I.V.)
Calcijex
Compazine
Darvon
Decadurobolin
Demerol
Depotestoserone
Desferal
Dijoxcin
Dilantin
Energix-B
Folic acid
Fortaz
Gentamicin
Hydro-cortisone
Imferon
Lanoxin
Mannitol
NaHCO3
Narcan
Premarin
Phenergan
Prolixin Decanoate
Promethazine
Recombivax
Rocephin
Talwin
Tobramycin
Urokinase
Valium (I.V.)
Vancomycin
Verapamil
Vitamin-B12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Memorandum

Date JUL 28 1992

From William Toby, Jr.
Acting Administrator

Subject Office of Inspector General (OIG) Draft Management Advisory Report: Cost of Dialysis-Related Drugs (A-01-91-00526)

To Inspector General
Office of the Secretary

We have reviewed the above-referenced draft management advisory report which summarizes the results of OIG's review of the Health Care Financing Administration's (HCFA) proposal to change the methodology for reimbursing separately billable drugs under Medicare's end stage renal disease (ESRD) program.

On June 5, 1991, HCFA published a proposal to change the methodology for reimbursing drugs under the Medicare ESRD program to 85 percent of the national average wholesale price (AWP) of the drug as published in the Drug Topics Red Book and similar price listings. On November 25, 1991, HCFA published final regulations (effective January 1) basing the reimbursement for separately billable drugs on the payment methodology for single-source and multiple-source drugs. Prior to the new regulations, ESRD facilities were reimbursed at the lower of the facility's customary charge, the actual charge, or the AWP. At the request of HCFA, OIG initiated the review to (1) determine the impact of paying dialysis facilities for drugs based on the proposed regulations, and (2) obtain the necessary data to include payment for certain high volume, separately billable, dialysis-related drugs under the prospective composite rate.

OIG found that dialysis facilities purchased separately billable drugs significantly below the national AWP. OIG recommends that HCFA:

- Provide intermediaries with the instructions needed to implement the new drug reimbursement policy promulgated in the Physician Payment Reform regulation;
- Encourage facilities to purchase drugs from the most economical source: and
- Place reimbursement for separately billable drugs in the composite rate.

We agree with the first two recommendations and defer comment on the third recommendation pending additional information from OIG. Our detailed comments are attached.

Thank you for the opportunity to review and comment on this draft management advisory report. Please advise us whether you agree with our position on the report's recommendations at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration
on Office of Inspector General (OIG) Draft Management Advisory Report:
Cost of Dialysis-Related Drugs
(A-01-91-00526)

OIG Recommendation

HCFA should provide the necessary guidance to the fiscal intermediaries to ensure a timely implementation of the estimated acquisition cost (EAC) provisions of the new Medicare drug regulations.

HCFA Response

We agree. We are in the process of developing a Medicare Carrier Manual instruction to limit drug payment to the lower of average wholesale price (AWP) or EAC. We plan to refer the intermediary processing the claim for ESRD separately billable drugs to the appropriate carrier for the calculation of the EAC and the AWP. Carriers are better able to make these calculations than are intermediaries, in the same sense that intermediaries look to carriers for the calculation of laboratory fee schedule amounts.

OIG Recommendation

HCFA should encourage providers to purchase drugs from the most economical source as required by the prudent buyer concept.

HCFA Response

We agree. As OIG notes, financial pressures created by the implementation of the new EAC methodology for pricing separately billable drugs should encourage providers to purchase their drugs from the most economical source. Apart from implementing the new payment methodology, no additional action is needed on the part of HCFA.

OIG Recommendation

HCFA should consider a methodology for folding the costs of all separately billable drugs into the composite rate.

HCFA Response

We defer comment on this recommendation until OIG responds to the following questions. OIG indicates that only freestanding ESRD facilities were surveyed. On what basis does OIG assume that the experience of hospital-based facilities in regard to the use of drugs is the same as that of freestanding facilities? OIG also indicates that the cost of separately billable drugs represents 3.2 percent of total facility costs for the facilities in the study. What was the variation in this percentage among the facilities?